General

Guideline Title

2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society.

Bibliographic Source(s)

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC): National Heart, Lung and Blood Institute (NHLBI) Evidence Statements are included for each recommendation. See Section 3 in the original guideline document.

Each recommendation has been mapped from the NHLBI grading format to the American College of Cardiology/American Heart Association Class of Recommendation/Level of Evidence (ACC/AHA COR/LOE) construct and is expressed in both formats. Because of the inherent differences in grading systems and the clinical questions driving the recommendations, alignment between the NHLBI and ACC/AHA formats is in some cases imperfect. Definitions for the NHLBI strength of recommendation (A-E, N) and quality of evidence (High, Moderate, Low) and the ACC/AHA levels of the evidence (LOE: A-C) and classes of recommendations (COR: I-III) are provided at the end of the "Major Recommendations" field.

<u>Summary of Recommendations for Obesity</u>

Identifying Patients Who Need to Lose Weight (Body Mass Index [BMI] and Waist Circumference)

1a. Measure height and weight and calculate BMI at annual visits or more frequently. NHLBI Grade: E (Expert Opinion); ACC/AHA COR: I; ACC/AHA LOE: C

1b. Use the current cutpoints for overweight (BMI 25.0–29.9 kg/m^2) and obesity (BMI ≥30 kg/m^2) to identify adults who may be at elevated risk

of cardiovascular disease (CVD) and the current cutpoints for obesity (BMI $\geq$30 kg/m^2) to identify adults who may be at elevated risk of mortality from all causes. NHLBI Grade: A (Strong); ACC/AHA COR: I; ACC/AHA LOE: B

1c. Advise overweight and obese adults that the greater the BMI, the greater the risk of CVD, type 2 diabetes, and all-cause mortality. NHLBI Grade: A (Strong) ACC/AHA COR: I; ACC/AHA LOE: B

1d. Measure waist circumference at annual visits or more frequently in overweight and obese adults. Advise adults that the greater the waist circumference, the greater the risk of CVD, type 2 diabetes, and all-cause mortality. The cutpoints currently in common use (from either National Institutes of Health [NIH]/NHLBI or World Health Organization/International Diabetes Federation [WHO/IDF]) may continue to be used to identify patients who may be at increased risk until further evidence becomes available. NHLBI Grade: E (Expert Opinion); ACC/AHA COR: IIa; ACC/AHA LOE: B

Matching Treatment Benefits with Risk Profiles (Reduction in Body Weight Effect on Risk Factors for CVD, Events, Morbidity and Mortality)

2. Counsel overweight and obese adults with cardiovascular risk factors (high blood pressure [BP], hyperlipidemia, and hyperglycemia) that lifestyle changes that produce even modest, sustained weight loss of 3% to 5% produce clinically meaningful health benefits, and greater weight losses produce greater benefits NHLBI Grade: A (Strong) ACC/AHA COR: I; ACC/AHA LOE: A.

a. Sustained weight loss of 3% to 5% is likely to result in clinically meaningful reductions in triglycerides, blood glucose, hemoglobin A1c, and the risk of developing type 2 diabetes.

b. Greater amounts of weight loss will reduce BP, improve low-density lipoprotein cholesterol (LDL-C) and high-density lipoprotein cholesterol (HDL-C), and reduce the need for medications to control BP, blood glucose, and lipids as well as further reduce triglycerides and blood glucose.

Diets for Weight Loss (Dietary Strategies for Weight Loss)

3a. Prescribe a diet to achieve reduced calorie intake for obese or overweight individuals who would benefit from weight loss, as part of a comprehensive lifestyle intervention. Any one of the following methods can be used to reduce food and calorie intake: NHLBI Grade: A (Strong); ACC/AHA COR: I; ACC/AHA LOE: A

a. Prescribe 1,200–1,500 kcal/d for women and 1,500–1,800 kcal/d for men (kilocalorie levels are usually adjusted for the individual's body weight)

b. Prescribe a 500-kcal/d or 750-kcal/d energy deficit or

c. Prescribe one of the evidence-based diets that restricts certain food types (such as high-carbohydrate foods, low-fiber foods, or high-fat foods) in order to create an energy deficit by reduced food intake.

3b. Prescribe a calorie-restricted diet for obese and overweight individuals who would benefit from weight loss, based on the patient's preferences and health status, and preferably refer to a nutrition professional* for counseling. A variety of dietary approaches can produce weight loss in overweight and obese adults, as presented in critical question (CQ) 3, evidence statement (ES) 2. NHLBI Grade: A (Strong); ACC/AHA COR: I; ACC/AHA LOE: A

Lifestyle Intervention and Counseling (Comprehensive Lifestyle Intervention)

4a. Advise overweight and obese individuals who would benefit from weight loss to participate for $\geq$6 months in a *comprehensive lifestyle program* that assists participants in adhering to a lower-calorie diet and in increasing physical activity through the use of behavioral strategies. NHLBI Grade: A (Strong); ACC/AHA COR: I; ACC/AHA LOE: A

4b. Prescribe on-site, high-intensity (i.e., $\geq$14 sessions in 6 mo) comprehensive weight loss interventions provided in individual or group sessions by a trained interventionist.† NHLBI Grade: A (Strong); ACC/AHA COR: I; ACC/AHA LOE: A

4c. Electronically-delivered weight loss programs (including by telephone) that include personalized feedback from a trained interventionist† can be prescribed for weight loss but may result in smaller weight loss than face-to-face interventions. NHLBI Grade: B (Moderate); ACC/AHA COR: IIa; ACC/AHA LOE: A

4d. Some commercial-based programs that provide a comprehensive lifestyle intervention can be prescribed as an option for weight loss, provided there is peer-reviewed published evidence of their safety and efficacy. NHLBI Grade: B (Moderate); ACC/AHA COR: IIa; ACC/AHA LOE: A

4e. Use a very-low-calorie diet (defined as <800 kcal/d) only in limited circumstances and only when provided by trained practitioners in a medical care setting where medical monitoring and high-intensity lifestyle intervention can be provided. Medical supervision is required because of

the rapid rate of weight loss and potential for health complications. NHLBI Grade: A (Strong); ACC/AHA COR: IIa‡ ACC/AHA LOE: A

4f. Advise overweight and obese individuals who have lost weight to participate long term (≥1 year) in a comprehensive weight loss maintenance program. NHLBI Grade: A (Strong); ACC/AHA COR: I; ACC/AHA LOE: A

4g. For weight loss maintenance, prescribe face-to-face or telephone-delivered weight loss maintenance programs that provide regular contact (monthly or more frequently) with a trained interventionist† who helps participants engage in high levels of physical activity (i.e., 200–300 min/wk), monitor body weight regularly (i.e., weekly or more frequently), and consume a reduced-calorie diet (needed to maintain lower body weight). NHLBI Grade: A (Strong); ACC/AHA COR: I; ACC/AHA LOE: A

Selecting Patients for Bariatric Surgical Treatment for Obesity (Bariatric Surgical Treatment for Obesity)

5a. Advise adults with a BMI ≥40 kg/m^2 or BMI ≥35 kg/m^2 with obesity-related comorbid conditions who are motivated to lose weight and who have not responded to behavioral treatment with or without pharmacotherapy with sufficient weight loss to achieve targeted health outcome goals that bariatric surgery may be an appropriate option to improve health and offer referral to an experienced bariatric surgeon for consultation and evaluation. NHLBI Grade: A (Strong); ACC/AHA COR: IIa§; ACC/AHA LOE: A

5b. For individuals with a BMI <35 kg/m^2, there is insufficient evidence to recommend for or against undergoing bariatric surgical procedures. NHLBI Grade: N (No Recommendation)

5c. Advise patients that choice of a specific bariatric surgical procedure may be affected by patient factors, including age, severity of obesity/BMI, obesity-related comorbid conditions, other operative risk factors, risk of short- and long-term complications, behavioral and psychosocial factors, and patient tolerance for risk, as well as provider factors (surgeon and facility). NHLBI Grade: E (Expert Opinion); ACC/AHA COR: IIb; ACC/AHA LOE: C

*Nutrition professional: In the studies that form the evidence base for this recommendation, a registered dietitian usually delivered the dietary guidance; in most cases, the intervention was delivered in university nutrition departments or in hospital medical care settings where access to nutrition professionals was available.

†Trained interventionist: In the studies reviewed, trained interventionists included mostly health professionals (e.g., registered dietitians, psychologists, exercise specialists, health counselors, or professionals in training) who adhered to formal protocols in weight management. In a few cases, lay persons were used as trained interventionists; they received instruction in weight management protocols (designed by health professionals) in programs that have been validated in high-quality trials published in peer-reviewed journals.

‡There is strong evidence that if a provider is going to use a very-low-calorie diet, it should be done with high levels of monitoring by experienced personnel; that does not mean that practitioners should prescribe very-low-calorie diets. Because of concern that an ACC/AHA Class I recommendation would be interpreted to mean that the patients should go on a very-low-calorie diet, it was the consensus of the Expert Panel that this maps more closely to an ACC/AHA Class IIa recommendation.

§There is strong evidence that the benefits of surgery outweigh the risks for some patients. These patients can be offered a referral to discuss surgery as an option. This does not mean that all patients who meet the criteria should have surgery. This decision-making process is quite complex and is best performed by experts. The ACC/AHA criterion for a Class I recommendation states that the treatment/procedure should be performed/administered. This recommendation as stated does not meet the criterion that the treatment should be performed. Thus, the ACC/AHA classification criteria do not directly map to the NHLBI grade assigned by the Expert Panel.

Definitions:

NHLBI Grading of the Strength of Recommendations

Grade	Strength of Recommendation*
A	Strong recommendation There is high certainty based on evidence that the net benefit† is substantial.
B	Moderate recommendation There is moderate certainty based on evidence that the net benefit is moderate to substantial, or there is high certainty that the net benefit is moderate.
C	Weak recommendation There is at least moderate certainty based on evidence that there is a small net benefit.
D	Recommendation against There is at least moderate certainty based on evidence that there is no net benefit or that risks/harms outweigh benefits.
E	Expert opinion ("There is insufficient evidence or evidence is unclear or conflicting, but this is what the Work Group recommends.") Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear

Grade	Strength of Recommendation*

N	No recommendation for or against ("There is insufficient evidence or evidence is unclear or conflicting.") Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, and the Work Group thought no recommendation should be made. Further research is recommended in this area.

*In most cases, the strength of the recommendation should be closely aligned with the quality of the evidence; however, under some circumstances, there may be valid reasons for making recommendations that are not closely aligned with the quality of the evidence (e.g., strong recommendation when the evidence quality is moderate, such as smoking cessation to reduce cardiovascular disease [CVD] risk or ordering an electrocardiogram [ECG] as part of the initial diagnostic work-up for a patient presenting with possible myocardial infarction [MI]). Those situations should be limited and the rationale explained clearly by the Work Group.

†Net benefit is defined as benefits minus risks/harms of the service/intervention.

NHLBI Quality Rating of the Strength of Evidence

Type of Evidence	Quality Rating*
• Well-designed, well-executed† randomized controlled trials (RCTs) that adequately represent populations to which the results are applied and directly assess effects on health outcomes. • Meta-analyses of such studies. Highly certain about the estimate of effect. Further research is unlikely to change confidence in the estimate of effect.	High
• RCTs with minor limitations‡ affecting confidence in, or applicability of, the results. • Well-designed, well-executed nonrandomized controlled studies§ and well-designed, well-executed observational studies¶. • Meta-analyses of such studies. Moderately certain about the estimate of effect. Further research may have an impact on confidence in the estimate of effect and may change the estimate.	Moderate
• RCTs with major limitations. • Nonrandomized controlled studies and observational studies with major limitations affecting confidence in, or applicability of, the results. • Uncontrolled clinical observations without an appropriate comparison group (e.g., case series, case reports). • Physiological studies in humans. • Meta-analyses of such studies. Low certainty about the estimate of effect. Further research is likely to have an impact on confidence in the estimate of effect and is likely to change the estimate.	Low

*In some cases, other evidence, such as large all-or-none case series (e.g., jumping from airplanes or tall structures), can represent high- or moderate-quality evidence. In such cases, the rationale for the evidence rating exception should be explained by the Work Group and clearly justified.

†"Well-designed, well-executed" refers to studies that directly address the question; use adequate randomization, blinding, and allocation concealment; are adequately powered; use intention-to-treat analyses; and have high follow-up rates.

‡Limitations include concerns with the design and execution of a study that result in decreased confidence in the true estimate of the effect. Examples of such limitations include but are not limited to: inadequate randomization, lack of blinding of study participants or outcome assessors, inadequate power, outcomes of interest that are not prespecified for the primary outcomes, low follow-up rates, and findings based on subgroup analyses. Whether the limitations are considered minor or major is based on the number and severity of flaws in design or execution. Rules for determining whether the limitations are considered minor or major and how they will affect rating of the individual studies will be developed collaboratively with the methodology team.

§Nonrandomized controlled studies refer to intervention studies where assignment to intervention and comparison groups is not random (e.g., quasi-experimental study design).

¶Observational studies include prospective and retrospective cohort, case-control, and cross-sectional studies.

Applying Classification of Recommendations and Level of Evidence

		Size of Treatment Effect				
		CLASS I *Benefit >>> Risk* Procedure/Treatment SHOULD be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* IT IS REASONABLE to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment MAY BE CONSIDERED	CLASS III *No Benefit* or Class III *Harm*	
						Procedure/Test	**Treatment**
					COR III: No Benefit	Not helpful	No proven benefit

Estimate of Certainty (Precision) of Treatment Effect			Size of Treatment Effect		COR III: Harm		
						Excess cost without benefit or harmful	Harmful to patients
Estimate of Certainty (Precision) of Treatment Effect	LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	• Recommendation that procedure or treatment is useful/effective • Sufficient evidence from multiple randomized trials or meta-analyses	• Recommendation in favor of treatment or procedure being useful/effective • Some conflicting evidence from multiple randomized trials or meta-analyses	• Recommendation's usefulness/efficacy less well established • Greater conflicting evidence from multiple randomized trials or meta-analyses		• Recommendation that procedure or treatment is not useful/effective and may be harmful • Sufficient evidence from multiple randomized trials or meta-analyses	
	LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	• Recommendation that procedure or treatment is useful/effective • Evidence from single randomized trial or nonrandomized studies	• Recommendation in favor of treatment or procedure being useful/effective • Some conflicting evidence from single randomized trial or nonrandomized studies	• Recommendation's usefulness/efficacy less well established • Greater conflicting evidence from single randomized trial or nonrandomized studies		• Recommendation that procedure or treatment is not useful/effective and may be harmful • Evidence from single randomized trial or nonrandomized studies	
	LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	• Recommendation that procedure or treatment is useful/effective • Only expert opinion, case studies, or standard of care	• Recommendation in favor of treatment or procedure being useful/effective • Only diverging expert opinion, case studies, or standard of care	• Recommendation's usefulness/efficacy less well established • Only diverging expert opinion, case studies, or standard of care		• Recommendation that procedure or treatment is not useful/effective and may be harmful • Only expert opinion, case studies, or standard of care	

A recommendation with Level of Evidence B or C does not imply the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Even when randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative-effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

Clinical Algorithm(s)

An algorithm titled "Treatment Algorithm-Chronic Disease Management Model for Primary Care of Patients with Overweight and Obesity" is provided in the original guideline document.

Scope

Disease/Condition(s)

- Overweight and obesity
- Cardiovascular disease (CVD) risk factors (hypertension, dyslipidemia, prediabetes, diabetes) or other obesity-related medical conditions

Guideline Category

Counseling

Evaluation

Management

Prevention

Risk Assessment

Clinical Specialty

Cardiology

Endocrinology

Family Practice

Internal Medicine

Nutrition

Preventive Medicine

Surgery

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Dietitians

Health Care Providers

Nurses

Pharmacists

Physician Assistants

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Guideline Objective(s)

To develop clinical practice guidelines for management of overweight and obesity in adults

Target Population

Overweight and obese adult patients

Interventions and Practices Considered

1. Identifying patients who need to lose weight by body mass index (BMI), waist circumference, and cardiometabolic risk factors
2. Identifying risk of cardiovascular disease (CVD) and other comorbidities
3. Advising patients about risk of CVD, type 2 diabetes, and all-cause mortality
4. Matching treatment benefits with risk profiles
5. Counseling overweight and obese patients with CVD risk factors on the benefits of lifestyle changes to lose weight
6. Diets for weight loss (calorie restriction, restriction of certain food types)
7. Lifestyle intervention and counseling (comprehensive lifestyle interventions that include lower-calorie diets and increasing physical activity)
   - Face-to-face programs
   - Electronically delivered programs
   - Commercial-based programs
   - Very-low-calorie diets (in limited circumstances)
   - Maintenance programs
8. Selecting and referring patients for bariatric surgical treatment

Major Outcomes Considered

- Reduction in body weight as measured by:
  - Weight (kg, lb, %)
  - Body fat measures (body mass index [BMI] and BMI change)
  - Waist circumference
  - Weight loss maintenance
- Cardiovascular disease (CVD) events
  - Myocardial infarction
  - Heart failure
  - Hospitalization for heart failure or stroke
- CVD risk factors
  - Systolic blood pressure or diastolic blood pressure
  - Total cholesterol, high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), non-HDL-C, triglycerides
  - Fasting insulin, fasting glucose, glycosylated hemoglobin, diagnosis of diabetes
  - C-reactive protein (CRP)
- Morbidity
  - Coronary heart disease/CVD
  - Type 2 diabetes
- Mortality (CVD-related, all-cause, overall)

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Infrastructure, Search Strategy Development, and Validation

The literature search was performed using an integrated suite of search engines that explored a central repository of citations and full text journal articles. The central repository, search engines, search results, and web-based modules for literature screening and data abstraction were integrated within a technology platform called the Virtual Collaborative Workspace (VCW). The VCW was custom-developed for the National Heart, Lung and Blood Institute (NHLBI) guidelines initiative.

The central repository consisted of 1.9 million citations and 71,000 full text articles related to cardiovascular disease (CVD) risk reduction. Citations were acquired from PubMed, EMBASE, CINAHL, Cochrane, PsycINFO, Wilson Science, and Biological Abstracts databases. Literature searches were conducted using a collection of search engines including: TeraText, Content Analyst, and Collexis, and Lucene. These engines were used for executing search strategies; Lucene was used in correlating the search with screening results.

For every critical question (CQ), a literature search and screening were conducted according to the understanding of the question and the inclusion and exclusion (I/E) criteria that provided specific characteristics of studies relevant to the question. Criteria were framed in the PICOTS format. Using Boolean and conceptual queries, the question and PICOTS components were translated into a search strategy.

A Boolean query encodes I/E rules. It grants access to the maximum quantity of citations, which are then analyzed by text analytics tools and ranked to produce a selection for literature screening. Two independent reviewers conducted the screening in the VCW's web-based module. Boolean queries select citations by matching words in titles and abstracts, as well as Medical Subject Headings (MeSH) and subheadings. The number of citations resulting from Boolean queries has ranged from a few hundred to several thousand depending on the question. The text analytics tools suite included:

- A natural language processing module for automated extraction of data elements to support the application of I/E criteria. Data elements that were frequently extracted and used were study size and intervention follow-up period.
- Content Analyst for automatically expanding vocabulary of queries, conceptual retrieval, and conceptual clustering. The conceptual query engine employed in Content Analyst leverages word frequency features and co-occurrence in similar contexts to index, select and rank results. The indexing uses the Singular Value Decomposition (SVD) algebraic method.
- TeraText for ranking search results and a variety of fast operations on the inverted index.

Search strategy development was intertwined with the results of literature screening, which provided feedback on search quality and context. Screened literature was categorized into two subsets: relevant or not relevant to the question. Next, results were analyzed to determine the characteristics of relevant versus not relevant citations. Additional keywords and MeSH terms were used to expand or contract the scope of the query as driven by characteristics of relevant citations. If a revised search strategy produced more citations than the original strategy, the new batch of citations was added for literature review. The search strategy refinement/literature review cycle was repeated until all citations covered by the most recent Boolean query had been screened.

Each search strategy was developed and implemented in the VCW. The methodologist and panel members reviewed the search strategy, which was available for viewing and printing at any time by panel members and staff collaborating on the systematic review. The search strategy was available for execution and supplying literature updates until the literature search and screening cut-off date.

An independent methodology team validated the search strategies for a sample of questions. As part of this validation process, the methodology team developed and executed a separate search strategy and screened a random sample of citations against I/E criteria. Then, these results were compared to the search and screening results developed by the systematic review team. Based on the validation process, the searches were considered appropriate. In addition, studies identified in SRs and MAs were cross-checked against a CQ's list of studies included in the evidence base to ensure completeness of the search strategy.

Process for Literature Review

Using results of the search strategy, criteria were applied to screen literature for inclusion or exclusion in the evidence base for the CQ. I/E criteria address the parameters in the PICOTS framework and determine what types of studies are eligible and appropriate to answer the CQ. When appropriate, the panel members added (with guidance from the methodology team) I/E criteria, such as sample size restrictions, to fit the context of the CQ. To enhance the quality of the abstracted literature, these criteria were applied uniformly (by the systematic review and methodology teams) within a given question.

Pilot Literature Screening Mode

In the Pilot Literature Screening Mode, two reviewers independently screened the first 50 titles/abstracts in the search strategy results by applying I/E criteria. Reviewers voted to include or exclude the publication for full text review. To ensure I/E criteria were applied consistently, they compared their results. Discrepancies in votes were discussed, and clarification on criteria was sought from the panel when appropriate. For example, if criteria were not specific enough to be clearly applied to include or exclude a citation, they sought guidance to more explicitly word criteria.

During this phase, reviewers provided feedback to the literature search team about the relevance of search strategy results; the team used this feedback to further refine and optimize the search.

Phase 1: Title and Abstract Screening Phase

After completing the Pilot Mode phase, two reviewers independently screened search results at the title and abstract level by applying I/E criteria. Reviewers voted to include or exclude the publication for full text review.

When at least one reviewer voted to include a publication based on the title and abstract review, the publication advanced to Phase 2, Full Text Screening. When both reviewers voted to exclude a publication, then it was excluded and not reviewed further. These citations are maintained in the VCW and marked as "excluded at title/abstract phase."

Phase 2: Full Text Screening Phase

In Phase 2, two reviewers independently applied I/E criteria to the full text article and voted "include," "exclude," or "undecided." The reviewer specified the rationale for exclusion (i.e., population, intervention, etc.) in this phase. Articles in which both reviewers voted "include" were moved to the Include List. Similarly, articles in which both reviewers voted to exclude were moved to the Exclude List. These citations were maintained in the VCW and identified as "excluded at the full article phase," and the rationale for exclusion was noted. Only articles with discrepant votes (i.e., one include and one undecided, one include and one exclude, and one exclude and one undecided.) advanced to Phase 3.

Phase 3: Resolution and Consultation Phase

In this phase, reviewers discussed their discrepant votes for include, exclude, or undecided and cited the relevant criteria for their decision. The two reviewers attempted to achieve consensus through collaborative discussion. If the reviewers could not reach consensus, they consulted the methodologist. If they were still unable to reach a consensus, they consulted the panel; however, the methodologist had the final decision. The final disposition of the article (include or exclude) was recorded in the VCW along with comments from the adjudication process.

Similar to search strategies being posted and available for viewing on the VCW, all citations screened for a CQ were maintained in the VCW with their reviewer voting status and collected comments.

Overview of Evidence-Based Methodology

The date for the overall literature search was from January 1998 to December 2009. Since CQ1 and CQ2 used systematic reviews and meta-analyses, the literature search included those published from January 2000 to October 2011. CQ3 and CQ4 added major randomized controlled trials (RCTs) published after 2009 with greater than 100 people per treatment arm and CQ5 added some major studies published after 2009 that met the I/E criteria.

Refer to Appendix 2 in the full panel report supplement for full details on the evidence-based process and Appendix 3 in the full panel report supplement for literature search strategies used for CQs (see the "Availability of Companion Documents" field) .

Number of Source Documents

Critical Question (CQ) 1 Search Strategy Results

The search produced 1,630 citations, with 3 additional citations identified from non-search sources (i.e., by the panel members). Two reviewers independently screened the titles and abstracts of 1,633 publications against the I/E criteria, resulting in 936 publications being excluded and 697 publications being retrieved for full-text review to further assess eligibility. Then, two reviewers independently screened and assessed the 697 full-text publications for eligibility by applying the I/E criteria; 669 of these publications were excluded based on one or more of the I/E criteria. Forty-two of the 697 full-text publications met the criteria and were included. The quality (internal validity) of these 42 publications was assessed using the quality assessment tool developed to assess systematic reviews (SRs)/meta-analyses (MAs) or randomized controlled trials (RCTs) (see Appendix 2 in the full panel report supplement [see the "Availability of Companion Documents" field]). Of these, 14 publications were rated poor quality; rationales for the poor quality studies are included in Appendix 3 of the full report. The remaining 28 publications were rated good or fair quality and included in the evidence base that was used to formulate the evidence statements and recommendations.

CQ2 Search Strategy Results

The search produced 1,566 citations, with 5 additional citations identified from non-search sources (i.e., by the panel members). Three of the five citations met the criteria and were eligible for inclusion in the CQ2 evidence base. In contrast, the other two citations did not meet the criteria and were excluded from the CQ2 evidence base. Two reviewers independently screened the titles and abstracts of 1,571 publications against the I/E criteria, resulting in 1,089 publications being excluded and 482 publications being retrieved for full-text review to further assess eligibility. Next, two reviewers independently screened and assessed 482 full-text publications for eligibility by applying the I/E criteria; 467 of these publications were excluded based on one or more of the I/E criteria. Fifteen of the 482 full-text publications met the criteria and were included. The quality (internal validity) of these 15 publications was assessed using the quality assessment tool developed to assess SRs/MAs (see Appendix 2 in the full panel report supplement [see the "Availability of Companion Documents" field]). Of these, 12 publications were rated as poor quality; however, they were used as part of the evidence base since National Heart Lung and Blood Institute (NHLBI) policy indicated that poor studies could be used as part of the evidence base if the majority of included studies were not rated good or fair. The remaining three SRs/MAs were rated good or fair quality and included in the evidence base that was used to formulate the evidence statements and recommendations.

CQ3 Search Strategy Results

The search produced 1,416 citations, with 6 additional citations identified from non-search sources, i.e., by panel members or hand search of SRs/MAs (obtained through the electronic search). Two reviewers independently screened the titles and abstracts of 1,422 publications against the I/E criteria, resulting in 984 publications being excluded and 438 publications being retrieved for full-text review to further assess eligibility. Next, two reviewers independently screened 438 full-text publications and assessed eligibility by applying the I/E criteria; 361 of these publications were excluded based on one or more of the I/E criteria. Furthermore, the CQ3 work group noted that since the focus of the CQ is solely on the effect of different dietary approaches to weight loss, other possible interventions could not differ. So, studies were excluded if treatment arms differed in their behavioral approach, i.e., the amount of participant contact and amount or method of prescribed physical activity. Seventy-seven of the 438

full-text publications met the criteria and were included. The quality (internal validity) of these 77 publications was assessed using the quality assessment tool developed to assess RCTs (see Appendix 2 in the full panel report supplement). Of these, 54 publications were excluded because they were rated as poor quality; 52 of these studies were rated poor due to the ITT and attrition rates. The remaining 17 RCTs (23 articles) were rated good or fair quality and included in the evidence base that was used.

CQ4 Search Strategy Results

The search produced 2,145 citations, with 15 additional citations identified from non-search sources, i.e., by the panel members or hand search of SRs/MAs (obtained through the electronic search). Of the 15 citations identified through non-search sources, 14 were screened and found eligible for inclusion; subsequently, two of these studies were rated as poor quality studies. Two reviewers independently screened the titles and abstracts of 2,160 publications against the I/E criteria, resulting in 1,776 publications being excluded and 384 publications being retrieved for full-text review to further assess eligibility. Next, two independent reviewers independently screened 384 full-text publications, assessing eligibility by applying the I/E criteria; 215 of these publications were excluded based on one or more of the I/E criteria. One hundred and forty-six of the 384 full-text publications met the criteria and were included. The quality (internal validity) of these 146 publications was assessed using the quality assessment tool developed to assess RCTs (see Appendix 2 in the full panel report supplement [see the "Availability of Companion Documents" field]). Of these, 74 publications were excluded because they were rated as poor quality; of them, 43 studies were rated poor due to the ITT and attrition rates. Rationales for the poor quality studies are included in Appendix 3 in the full panel report supplement (see the "Availability of Companion Documents" field). The remaining 51 trials (72 articles) were rated good or fair quality and included in the evidence base that was used to formulate the evidence statements and recommendations.

CQ5 Search Strategy Results

The search produced 2,317 citations, with 9 additional citations identified from nonsearch sources, that is, by Expert Panel members or hand search of systematic reviews and meta-analyses (obtained through the electronic search). Of the nine citations identified through non-search sources, four were screened and found eligible for inclusion; subsequently, all these studies were rated as good quality. Of the 2,317 citations identified through the database search, 811 citations were automatically excluded using the natural language processing filter. Two reviewers independently screened the remaining titles and abstracts of the 1,515 remaining citations against the I/E criteria for each of the three components (Efficacy, Predictors, and Complications). This resulted in 1,062 publications being excluded (on one or more of the I/E criteria for each of the three components of CQ5) and 453 publications being retrieved for full-text review to further assess eligibility. Sixty-four of the 453 full-text publications met the criteria and were included. The quality (internal validity) of these 64 publications was assessed using the six quality assessment tools that were developed (see Appendix 2 in the full panel report supplement). Of these, 29 publications were excluded because they were rated as poor quality; of these, 18 studies were rated poor due to the ITT and/or attrition rates. Rationales for the poor quality studies are included in Appendix 3 of the full report. The remaining 22 trials (35 articles) that met the criteria for at least one of the three components were rated good or fair quality and included in the evidence base. These articles were used to formulate the evidence statements and recommendations. For the Efficacy, Predictors and Complications components, there were 17, 12, and 15 citations rated as good/fair. There were a total of eight citations that were used across more than one component. Of the 16 citations included for the Efficacy component, 4 were RCTs, and 12 were observational studies. Of the 12 citations included for the Predictors component, 6 were RCTs and 6 were observational studies. And, of the 15 citations included for the Complications component, 4 were RCTs and 11 were observational studies.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Applying Classification of Recommendations and Level of Evidence

	Size of Treatment Effect					
	CLASS I *Benefit >>> Risk* Procedure/Treatment SHOULD be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* IT IS REASONABLE to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment MAY BE CONSIDERED	CLASS III *No Benefit* or Class III *Harm*		
					Procedure/Test	**Treatment**
				COR III: No Benefit	Not helpful	No proven benefit
				COR III: Harm	Excess cost without benefit or harmful	Harmful to patients

Estimate of Certainty (Precision) of Treatment Effect		Size of Treatment Effect			
	LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	• Recommendation that procedure or treatment is useful/effective • Sufficient evidence from multiple randomized trials or meta-analyses	• Recommendation in favor of treatment or procedure being useful/effective • Some conflicting evidence from multiple randomized trials or meta-analyses	• Recommendation's usefulness/efficacy less well established • Greater conflicting evidence from multiple randomized trials or meta-analyses	• Recommendation that procedure or treatment is not useful/effective and may be harmful • Sufficient evidence from multiple randomized trials or meta-analyses
	LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	• Recommendation that procedure or treatment is useful/effective • Evidence from single randomized trial or nonrandomized studies	• Recommendation in favor of treatment or procedure being useful/effective • Some conflicting evidence from single randomized trial or nonrandomized studies	• Recommendation's usefulness/efficacy less well established • Greater conflicting evidence from single randomized trial or nonrandomized studies	• Recommendation that procedure or treatment is not useful/effective and may be harmful • Evidence from single randomized trial or nonrandomized studies
	LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	• Recommendation that procedure or treatment is useful/effective • Only expert opinion, case studies, or standard of care	• Recommendation in favor of treatment or procedure being useful/effective • Only diverging expert opinion, case studies, or standard of care	• Recommendation's usefulness/efficacy less well established • Only diverging expert opinion, case studies, or standard of care	• Recommendation that procedure or treatment is not useful/effective and may be harmful • Only expert opinion, case studies, or standard of care

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative-effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

National Heart, Lung and Blood Institute (NHLBI) Quality Rating of the Strength of Evidence

Type of Evidence	Quality Rating*
• Well-designed, well-executed† randomized controlled trials (RCTs) that adequately represent populations to which the results are applied and directly assess effects on health outcomes. • Meta-analyses of such studies. Highly certain about the estimate of effect. Further research is unlikely to change confidence in the estimate of effect.	High
• RCTs with minor limitations‡ affecting confidence in, or applicability of, the results. • Well-designed, well-executed nonrandomized controlled studies§ and well-designed, well-executed observational studies¶. • Meta-analyses of such studies. Moderately certain about the estimate of effect. Further research may have an impact on confidence in the estimate of effect and may change the estimate.	Moderate
• RCTs with major limitations. • Nonrandomized controlled studies and observational studies with major limitations affecting confidence in, or applicability of, the results. • Uncontrolled clinical observations without an appropriate comparison group (e.g., case series, case reports). • Physiological studies in humans. • Meta-analyses of such studies. Low certainty about the estimate of effect. Further research is likely to have an impact on confidence in the estimate of effect and is likely to change the estimate.	Low

*In some cases, other evidence, such as large all-or-none case series (e.g., jumping from airplanes or tall structures), can represent high- or moderate-quality evidence. In such cases, the rationale for the evidence rating exception should be explained by the Work Group and clearly justified.

†"Well-designed, well-executed" refers to studies that directly address the question; use adequate randomization, blinding, and allocation concealment; are adequately powered; use intention-to-treat analyses; and have high follow-up rates.

‡Limitations include concerns with the design and execution of a study that result in decreased confidence in the true estimate of the effect. Examples of such limitations include but are not limited to: inadequate randomization, lack of blinding of study participants or outcome assessors, inadequate power, outcomes of interest that are not prespecified for the primary outcomes, low follow-up rates, and findings based on subgroup analyses. Whether the limitations are considered minor or major is based on the number and severity of flaws in design or execution. Rules for determining whether the limitations are considered minor or major and how they will affect rating of the individual studies will be developed collaboratively with the methodology team.

§Nonrandomized controlled studies refer to intervention studies where assignment to intervention and comparison groups is not random (e.g., quasi-experimental study design).

¶Observational studies include prospective and retrospective cohort, case-control, and cross-sectional studies.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Directed by the National Heart, Lung and Blood Institute (NHLBI), with input from the panels and work groups, the contractor staff:

- Determined, by two independent raters, the quality of each included study. The methodology staff, with NHLBI input, adapted study-rating instruments and trained study raters on the use of these instruments. Six quality assessment tools were designed to assist reviewers in the critical appraisal of a study's internal validity.
- Reviewers used the study ratings to judge each study to be of "good," "fair," or "poor" quality. The reviewers used the ratings to assess the risk of bias in the study due to flaws in study design or implementation.
- Abstracted relevant information from the included studies into an electronic central repository database. Templates with lists of data elements pertinent to the established inclusion/exclusion (I/E) criteria were constructed and used to support abstraction.
- Constructed detailed evidence tables to organize the data from the abstraction database.
- Analyzed the evidence tables and constructed summary tables, which display the evidence in a manageable format to answer specific parts of the critical question (CQ).

The Expert Panels and Work Groups:

- Used summary tables to develop evidence statements for each CQ. The quality of evidence for each evidence statement was graded as high, moderate, or low based on scientific methodology, scientific strength, and consistency of results (see the "Rating Scheme for the Strength of the Evidence" field). For CQ1 and CQ2, spreadsheets with relevant data from systematic reviews/meta-analyses rather than summary tables were developed.

See Appendix 2 in the full panel report supplement (see the "Availability of Companion Documents" field) for more details on the evidence-based process. The strength of the body of evidence represents the degree of certainty, based on the overall body of evidence, that an effect or association is correct. Appendix 2.6 of the full panel report supplement describes how four domains of the body of evidence—risk of bias, consistency, directness, and precision—were used to grade the strength of evidence.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The American College of Cardiology (ACC) and American Heart Association (AHA) have collaborated with the National Heart, Lung and Blood Institute (NHLBI) and stakeholder and professional organizations to develop clinical practice guidelines for assessment of cardiovascular risk, lifestyle modifications to reduce cardiovascular risk, management of blood cholesterol in adults, and management of overweight and obesity in adults.

In 2008, the NHLBI initiated these guidelines by sponsoring rigorous systematic evidence reviews for each topic by expert panels convened to develop critical questions (CQs), interpret the evidence, and craft recommendations. In response to the 2011 report from the Institute of Medicine on the development of trustworthy clinical guidelines, the NHLBI Advisory Council recommended that the NHLBI focus specifically on reviewing the highest-quality evidence and partner with other organizations to develop recommendations. Accordingly, in June 2013 the NHLBI initiated collaboration with the ACC and AHA to work with other organizations to complete and publish the guidelines and make them available to the widest possible constituency. Recognizing that the Expert Panels/Work Groups did not consider evidence beyond 2011 (except as specified in the methodology), the ACC, AHA, and collaborating societies plan to begin updating these guidelines starting in 2014.

The joint ACC/AHA Task Force on Practice Guidelines (Task Force) appointed a subcommittee to shepherd this transition, communicate the rationale and expectations to the writing panels and partnering organizations, and expeditiously publish the documents. The ACC/AHA and partner organizations recruited a limited number of expert reviewers for fiduciary examination of content, recognizing that each document had undergone extensive peer review by representatives of the NHLBI Advisory Council, key federal agencies, and scientific experts. Each writing panel responded to comments from these reviewers. Clarifications were incorporated where appropriate, but there were no substantive changes because the bulk of the content was undisputed.

Although the Task Force led the final development of these prevention guidelines, they differ from other ACC/AHA guidelines. First, as opposed to an extensive compendium of clinical information, these documents are significantly more limited in scope and focus on selected CQs on each topic based on the highest-quality evidence available. Recommendations were derived from randomized trials, meta-analyses, and observational studies evaluated for quality and were not formulated when sufficient evidence was not available. Second, the text accompanying each recommendation is succinct, summarizing the evidence for each question. The Full Panel/Work Group Reports (see the "Availability of Companion Documents" field) include more detailed information about the evidence statements (ESs) that serve as the basis for recommendations. Third, the format of the recommendations differs from other ACC/AHA guidelines. Each recommendation has been mapped from the NHLBI grading format to the ACC/AHA Classification of Recommendation/Level of Evidence (COR/LOE) construct (see the "Rating Scheme for the Strength of the Evidence" field) and is expressed in both formats. Because of the inherent differences in grading systems and the clinical questions driving the recommendations, alignment between the NHLBI and ACC/AHA formats is in some cases imperfect. Explanations of these variations are noted in the recommendation tables, where applicable.

CQ-Based Approach

The Expert Panel began its deliberations by developing 23 possible CQs, and after considerable discussion, narrowed the possibilities to 5 targeted CQs. Questions were chosen to aid primary care practitioners (PCPs) and providers who frequently work with obese patients to identify patients at health risk of weight-related comorbidities and to update them on the benefits and risks of weight loss achieved by various approaches. Examples of CQs that were not included for this review included consideration of genetics of obesity, binge-eating disorders, pharmacotherapy, and cost-effectiveness of interventions to manage obesity. For each of the chosen CQs, Expert Panel members reviewed the final list of included and excluded articles, along with the quality ratings, and had the opportunity to raise questions and appeal the ratings to the methodology team. The team then reexamined these articles and presented their rationale for either keeping or changing the quality rating of the articles. Expert Panel members also played a key role in examining the evidence tables and summary tables to be certain the data from each article were accurately displayed.

The body of the present report is organized by CQ and the following information is included for each CQ:

- The rationale for its selection is provided, and methods are described.
- The body of evidence is summarized, and evidence statements (ESs) are presented, which include a rating for quality and a supportive narrative summary.
- Recommendations and their strength are accompanied by a narrative summary of how the recommendation was derived from the evidence and a discussion of issues considered by the Expert Panel in formulating the recommendation.

CQ1 and CQ2 were chosen to help providers determine the appropriate criteria to guide a weight loss recommendation. CQ1 addresses the expected health benefits of weight loss as a function of the amount and duration of weight loss. CQ2 addresses the health risks of overweight and obesity and seeks to determine if the current waist circumference cutpoints and the widely accepted body mass index (BMI) cutpoints defining persons as overweight (BMI 25–29.9 kg/m^2) and obese (BMI ≥30 kg/m^2) are appropriate for population subgroups. Because patients are interested in popular diets that are promoted for weight loss and see the PCP as an authoritative source of information, CQ3 asks which dietary intervention strategies are effective for weight loss efforts. CQ4 seeks to determine the efficacy and effectiveness of a comprehensive lifestyle approach (diet, physical activity, and behavior therapy) to achieve and maintain weight loss. CQ5 seeks to determine the efficacy and safety of bariatric surgical procedures, including benefits and risks. CQ5 also seeks to determine patient and procedural factors that may help guide decisions to enhance the likelihood of maximum benefit from surgery for obesity and related conditions.

Organization of the Panel

In 2007, the NHLBI sought nominations for panel membership that would ensure adequate representation of key specialties and appropriate expertise. The NHLBI staff reviewed the nominees and selected potential chairs and co-chairs for the panels. A Guidelines Executive Committee was formed, consisting of the chairs from each of the 3 panels (obesity, high blood pressure [BP], and high blood cholesterol) and 3 cross-cutting working groups (lifestyle, risk assessment, and implementation). This committee worked with the NHLBI to select panel members from the list of nominees.

The Obesity Expert Panel comprised 15 members and 3 ex-officio members, including individuals with specific expertise in psychology, nutrition, physical activity, bariatric surgery, epidemiology, internal medicine, and other clinical specialties. The full Obesity Expert Panel met 23 times throughout the years (5 times face-to-face and 18 times via Webinar). Expert Panel chairs asked all members to disclose any conflicts of interest to the full Expert Panel in advance of the deliberations; members with conflicts were asked to recuse themselves from voting on any aspect of the guideline for which a conflict might exist. Each of the 5 CQs had working groups consisting of a leader and various Expert Panel members who met via conference calls to discuss all aspects of the CQ; to review the list of included and excluded articles along with the quality ratings; to review the evidence tables and summary tables; and to develop spreadsheets, ESs, resulting recommendations, and research/evidence gaps. Expert Panel members had the opportunity to raise questions about the included and excluded articles, submit additional articles that were not identified in the original search, appeal the quality ratings on articles, and question articles that were excluded. Each working group presented their findings to the full Expert Panel for all final decisions on ESs and recommendations, including the strength of the evidence.

The evidence-based process followed most of the standards from the Institute of Medicine's report, *Clinical Practice Guidelines We Can Trust*. The process had support from a methodology contractor and a systematic review and general support contractor.

Description of How Panels Developed and Prioritized Critical Questions

After panels were convened, members were invited to submit topic areas or questions for systematic review. Members were asked to identify topics of the greatest relevance and impact for the target audience of the guideline: PCPs.

Over several months, panel members submitted proposed questions and topic areas. The number of CQs was scoped and then prioritized based on resource constraints. After group discussion, panel members ranked priority CQs through collaborative dialogue and voting. The rationale for each priority CQ is addressed in the main report.

With support from the methodologist and systematic review team, panel members formulated priority CQs. They also developed inclusion and exclusion (I/E) criteria to ensure that criteria were clear and precise and could be applied consistently across literature identified in the search. Using I/E criteria, the PICOTS format (patient population, intervention/exposure, comparison group, outcome, timing, and setting) were defined and formatted.

I/E criteria define the parameters for selecting literature for a particular CQ. Panel members submitted final CQs and criteria to the literature search team to develop a search strategy. To gather the body of evidence for each CQ, they used two approaches: 1) to conduct a de novo literature search and review of all individual studies that met a CQ's I/E criteria. This approach was used for most critical questions; 2) to focus the literature search on existing systematic reviews (SRs) and meta-analyses (MAs), which summarized a broad range of the scientific literature. Several CQs across panels and work groups used this approach, which was developed in response to resource limitations for the project overall.

The five CQs are as follows:

CQ1: Among overweight and obese adults, does weight loss produce cardiovascular disease (CVD)-related health benefits and what health benefits can be expected with different degrees of weight loss?

CQ2: What are the CVD-related health risks of overweight and obesity and are the current cutpoints for overweight (body mass index [BMI] 25–29.9kg/m^2) and obesity (BMI >30kg/m^2) and waist circumference (>102 cm [M] and >88 cm [F]) appropriate for population subgroups?

CQ3: Which dietary intervention strategies are effective for weight loss?

CQ4: What is the efficacy/effectiveness of a comprehensive lifestyle intervention program (i.e., diet, physical activity, and behavior therapy) in facilitating weight loss or maintaining weight loss?

CQ5: What is the efficacy and safety of bariatric surgery? What is the profile (BMI and comorbidity type) of patients who might benefit from surgery for obesity and related conditions?

Process for the Development of Evidence Statements, Recommendations, and Panel Voting

Using the summary tables (and evidence tables as needed), panel members collaboratively wrote the evidence statements with input from methodology staff and oversight of the process by the NHLBI staff. Evidence statements aimed to summarize key messages from the evidence that could be provided to primary care providers and other stakeholders. In some cases, the evidence was too limited or inconclusive, so no evidence statement was developed, or a statement of insufficient evidence was made.

Voting occurred by a panel chair asking each member to signify his or her vote. The NHLBI project staff, methodologists, and contractors did not vote.

Once evidence statements were final, attention turned to developing recommendations. Recommendations were developed using a process similar to that used for evidence statements. For approval of a recommendation rated E (expert opinion) at least 75 percent of the expert panel members had to vote "yes." For both evidence statements and recommendations, voting could be open so that differing viewpoints could be identified easily and further discussion and revisions facilitated to address areas of disagreement (e.g., by crafting language or dividing an evidence statement into more than one statement). Voting also could be by confidential ballot if the group so chose.

For both evidence statements and recommendations, a record of the vote count (for, against, recusal) was made without attribution. The ideal was 100 percent consensus, but a 2/3 majority was considered acceptable. In cases where a 2/3 majority was not reached in the initial vote, further discussion and clarification was used to create a consensus majority.

Rating Scheme for the Strength of the Recommendations

Note: Each recommendation has been mapped from the National Heart, Lung and Blood Institute (NHLBI) grading format below to the American College of Cardiology/American Heart Association (ACC/AHA) Classification of Recommendation/Level of Evidence (COR/LOE) construct (see the "Rating Scheme for the Strength of the Evidence" field) and is expressed in both formats.

NHLBI Grading of the Strength of Recommendations

Grade	Strength of Recommendation*
A	Strong recommendation There is high certainty based on evidence that the net benefit† is substantial.
B	Moderate recommendation There is moderate certainty based on evidence that the net benefit is moderate to substantial, or there is high certainty that the net benefit is moderate.
C	Weak recommendation There is at least moderate certainty based on evidence that there is a small net benefit.
D	Recommendation against There is at least moderate certainty based on evidence that there is no net benefit or that risks/harms outweigh benefits.
E	Expert opinion ("There is insufficient evidence or evidence is unclear or conflicting, but this is what the Work Group recommends.") Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, but the Work Group thought it was important to provide clinical guidance and make a recommendation. Further research is recommended in this area.
N	No recommendation for or against ("There is insufficient evidence or evidence is unclear or conflicting.") Net benefit is unclear. Balance of benefits and harms cannot be determined because of no evidence, insufficient evidence, unclear evidence, or conflicting evidence, and the Work Group thought no recommendation should be made. Further research is recommended in this area.

*In most cases, the strength of the recommendation should be closely aligned with the quality of the evidence; however, under some circumstances, there may be valid reasons for making recommendations that are not closely aligned with the quality of the evidence (e.g., strong recommendation when the evidence quality is moderate, such as smoking cessation to reduce cardiovascular disease [CVD] risk or ordering an electrocardiogram [ECG] as part of the initial diagnostic work-up for a patient presenting with possible myocardial infarction [MI]). Those situations should be limited and the rationale explained clearly by the Work Group.

†Net benefit is defined as benefits minus risks/harms of the service/intervention.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Description of Method of Guideline Validation

A formal peer review process was initially completed under the auspices of the National Heart, Lung and Blood Institute (NHLBI) and included 10 expert reviewers and representatives from multiple federal agencies. This document was also reviewed by 6 expert reviewers nominated by the American College of Cardiology (ACC), the American Heart Association (AHA), and The Obesity Society after the management of the guideline transitioned to the ACC/AHA.

This document was approved for publication by the governing bodies of the ACC, the AHA, and The Obesity Society and is endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Pharmacists Association, American Society for Nutrition, American Society for Parenteral and Enteral Nutrition, American Society for Preventive Cardiology, American Society of Hypertension, Association of Black Cardiologists, National Lipid Association, Preventive Cardiovascular Nurses Association, The Endocrine Society, and WomenHeart: The National Coalition for Women With Heart Disease.

This document was approved by the American College of Cardiology Board of Trustees, the American Heart Association Science Advisory and Coordinating Committee, and The Obesity Society Board of Trustees in November 2013. The Academy of Nutrition and Dietetics affirms the value of this guideline.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management of overweight and obesity in adults

Potential Harms

- Bariatric surgery is, by definition, invasive and has inherent short-term risks as well as adverse effects that may become apparent only during longer-term follow-up.
- Perioperative complications of laparoscopic adjustable gastric banding (LAGB) are infrequent and do not tend to be life-threatening: major adverse outcomes (1%), such as deep venous thrombosis and reoperations, and minor complications (3%), such as wound infection. Longer-term complications continue to occur over time and may require operative correction: misplacement of band, approximately 3% to 4%; erosion of gastric wall, approximately 1%; and port complication, 5% to 11%. The rate of longer-term LAGB failure leading to removal of the band with or without conversion to another bariatric procedure varies from 2% to 34%. Inadequate weight loss is the most often reported basis for removal of band.
- Perioperative (≤30 days) and longer-term (>30 days) complications after bariatric surgery vary by procedure and patient-derived risk factors. When Roux-en-Y gastric bypass is performed by an experienced surgeon, perioperative complications consist of a major adverse outcome in approximately 4% to 5% of patients, including mortality (0.2%), deep vein thrombosis and/or pulmonary embolism (0.4%), and a need for reoperation (3% to 5%). The rate of any complication, major or minor, is 2% to 18%. When open gastric bypass is performed by an experienced surgeon, perioperative complications consist of a major adverse outcome in approximately 8% of patients, including mortality (2%), deep vein thrombosis or pulmonary embolism (1%), and a need for reoperation (5%). Perioperative complications are less frequent for the laparoscopic approach than for open incision.
- Perioperative (≤30 days) and longer-term (>30 days) complications after bariatric surgery vary by procedure and patient-derived risk factors. When biliopancreatic diversion (BPD) is performed by an experienced surgeon, perioperative complications occur in 2% to 8% of

cases and include mortality (<1%) and deep vein thrombosis or pulmonary embolism (0.4%). The frequency of anastomotic leak, hemorrhage, and wound complication is variable. One- to three-year complications include: anemia (13% to 20%); deficiency of protein (0.3% to 3.0%), iron (17%), or zinc (6%); and neuropathy (0.4%). Deficiency of vitamin D and elevated parathyroid hormone may exceed 40%. When BPD is performed by open incision, the rate of ventral hernia can be as high as 72%.

- Medical supervision is required when very-low-calorie (<800 kcal/day) are used because of the rapid rate of weight loss and potential for health complications.

Qualifying Statements

Qualifying Statements

These guidelines are meant to define practices that meet the needs of patients in most circumstances and are not a replacement for clinical judgment. The ultimate decision about care of a particular patient must be made by the healthcare provider and patient in light of the circumstances presented by that patient. As a result, situations might arise in which deviations from these guidelines may be appropriate. These considerations notwithstanding, in caring for most patients, clinicians can employ the recommendations confidently to reduce the risks of atherosclerotic cardiovascular disease (CVD) events.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Clinical Algorithm

Patient Resources

Pocket Guide/Reference Cards

Resources

Slide Presentation

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Jensen MD, Ryan DH, Apovian CM, Ard JD, Comuzzie AG, Donato KA, Hu FB, Hubbard VS, Jakicic JM, Kushner RF, Loria CM, Millen BE, Nonas CA, Pi-Sunyer FX, Stevens J, Stevens VJ, Wadden TA, Wolfe BM, Yanovski SZ. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. J Am Coll Cardiol. 2014 Jul 1;63(25 Pt B):2985-3023. [173 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014 Jul 1

Guideline Developer(s)

American College of Cardiology Foundation - Medical Specialty Society

American Heart Association - Professional Association

The Obesity Society - Disease Specific Society

Source(s) of Funding

Development of the systematic review (see the "Availability of Companion Documents" field) was funded by the United States Government.

Development of the guideline was funded by the American College of Cardiology, the American Heart Association, and The Obesity Society.

Guideline Committee

Obesity Expert Panel

American College of Cardiology/American Heart Association Task Force on Practice Guidelines

Subcommittee on Prevention Guidelines

Composition of Group That Authored the Guideline

Expert Panel Members: Michael D. Jensen, MD (*Co-Chair*); Donna H. Ryan, MD (*Co-Chair*); Caroline M. Apovian, MD, FACP; Jamy D. Ard, MD; Anthony G. Comuzzie, PHD; Karen A. Donato, SM*; Frank B. Hu, MD, PhD, FAHA; Van S. Hubbard, MD, PHD*; John M. Jakicic, PHD; Robert F. Kushner, MD; Catherine M. Loria, PhD, FAHA*; Barbara E. Millen, DrPH, RD; Cathy A. Nonas, MS, RD; F. Xavier Pi-Sunyer, MD, MPH; June Stevens, PhD; Victor J. Stevens, PhD; Thomas A. Wadden, PhD; Bruce M. Wolfe, MD; Susan Z. Yanovski, MD*

Methodology Members: Harmon S. Jordan, SCD; Karima A. Kendall, PHD; Linda J. Lux; Roycelynn Mentor-Marcel, PhD, MPH; Laura C. Morgan, MA; Michael G. Trisolini, PhD, MBA; Janusz Wnek, PhD

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Subcommittee on Prevention Guidelines: Sidney C. Smith, Jr, MD, FACC, FAHA (*Chair*); Gordon F. Tomaselli, MD, FACC, FAHA (*Co-Chair*)

Financial Disclosures/Conflicts of Interest

In consultation with the National Heart, Lung and Blood Institute (NHLBI), the policies adopted by the writing panels to manage relationships of authors with industry and other entities (RWI) are outlined in the methods section of each panel report. These policies were in effect when this effort began in 2008 and throughout the writing process and voting on recommendations, until the process was transferred to the American College of Cardiology/American Heart Association (ACC/AHA) in 2013. In the interest of transparency, the ACC/AHA requested that panel authors resubmit RWI disclosures as of July 2013. Relationships relevant to this guideline are disclosed in Appendix 1 of the original guideline document. None of the ACC/AHA expert reviewers had relevant RWI (Appendix 2 in the original guideline document).

Panel members having RWI or other possible conflicts of interest (COI) were allowed to participate in discussions leading up to voting as long as they declared their relationships, but they recused themselves from voting on any issue relating to their RWI or potential COI.

Guideline Endorser(s)

American Association of Cardiovascular and Pulmonary Rehabilitation - Medical Specialty Society

American Pharmacists Association - Professional Association

American Society for Parenteral and Enteral Nutrition - Professional Association

American Society for Preventive Cardiology - Medical Specialty Society

American Society of Hypertension - Disease Specific Society

Association of Black Cardiologists - Medical Specialty Society

Preventive Cardiovascular Nurses Association - Medical Specialty Society

The Endocrine Society - Professional Association

WomenHeart: The National Coalition for Women with Heart Disease - Nonprofit Organization

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the Journal of the American College of Cardiology (ACC) Web site [_____], the Circulation Web site [_____], and the Obesity Society Web site [_____].

Print copies: Available from the ACC, 2400 N Street NW, Washington DC, 20037; (800) 253-4636 (US only).

Availability of Companion Documents

The following are available:

- Jensen MD, Ryan DH, Donato KA, Apovian CM, Ard JD, Comuzzie AG, Hu FB, Hubbard VS, Jakicic JM, Kushner RF, Loria CM, Millen BE, Nonas CA, Pi-Sunyer FX, Stevens J, Stevens VJ, Wadden TA, Wolfe BM, Yanovski SZ. Guidelines (2013) for managing overweight and obesity in adults. Obesity 2014;22(S2):S1-S410. Electronic copies: Available from the Obesity Web site   .
- Obesity Expert Panel. Managing overweight and obesity in adults. Systematic evidence review from the Obesity Expert Panel. Bethesda (MD): National Heart, Lung and Blood Institute (NHLBI); 2013. 501 p. Electronic copies: Available from the National Heart, Lung and Blood Institute (NHLBI) Web site   .
- 2013 report on the management of overweight and obesity in adults: full panel report supplement. 2013. 396 p. Electronic copies: Available from the Journal of the American College of Cardiology Web site   .
- 10 points to remember. Available from the American College of Cardiology (ACC) Web site   . Also available as a video from the ACC Web site   .
- 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults. Slide set. 2013. 22 p. Electronic copies: Available from the ACC Web site   .
- 2013 prevention guideline case vignettes. Available from the ACC Web site   .
- Methodology manual and policies from the ACCF/AHA Task Force on Practice Guidelines. 2010 Jun. 88 p. American College of Cardiology Foundation and American Heart Association, Inc. Electronic copies: Available from the ACC Web site   .

Print copies: Available from the ACC, 2400 N Street NW, Washington DC, 20037; (800) 253-4636 🔁 (US only).

A pocket guideline is available from the Guideline Central Web site   .

Patient Resources

The following is available:

- Guidelines for treating overweight and obesity. Patient resource. Available from the American College of Cardiology (ACC) Web site   .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

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